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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,643	12/01/2000	Steven M. Ruben	PZ040P1	2092

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EXAMINER
SPIEGLER, ALEXANDER H

ART UNIT	PAPER NUMBER
1656	6

DATE MAILED: 12/12/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/726,643	Applicant(s) RUBEN ET AL.	
	Examiner Alexander H. Spiegler	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *05 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10 and 21, drawn to polynucleotides from an expressed sequence tag library for use in detecting altered expression, classified in class 536, subclass 23.1.

II. Claims 11-12 and 14, drawn to a purified polypeptide encoded by a polynucleotide from an EST library, classified in class 530, subclass 300.

III. Claim 13, drawn to an antibody to a polypeptide, classified in class 530, subclass 387.9.

IV. Claim 15-16, drawn to a method of making a polypeptide by culturing a host cell, and the polypeptide produced, classified in class 435, subclass 70.1

V. Claim 17, drawn to a method of treatment by administering an isolated polypeptide, classified in class 514, subclass 2.

VI. Claim 17, drawn to a method for preventing, treating, or ameliorating a medical condition using a polynucleotide, classified in class 514, subclass 1.

VII. Claim 18, drawn to a method of diagnosing a disease using an isolated polynucleotide, classified in class 435, subclass 6.

VIII. Claim 19, drawn to a method of diagnosing a disease using an isolated polypeptide, classified in class 435, subclass 5.

IX. Claims 20 and 23, drawn to a method of identifying a binding partner for a polypeptide, classified in class 436, subclass 501.

X. Claim 22, drawn to a method of identifying a biological activity, classified in class 436, subclass 9.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are separate and distinct because the inventions are directed to different chemical types regarding the critical limitations therein. For Group II, the critical feature is a polypeptide, whereas for Group I the critical feature is a polynucleotide. It is acknowledged that various processing steps may cause a polypeptide of group II to be directed as to its synthesis by a polynucleotide of Group I, however, the completely separate chemical types of the inventions of Groups I and II supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examiner together, as compared to being searched separately. Also, it is pointed out that processing that may connect two groups does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

Inventions I and III are separate and distinct, as the claims of Invention I are drawn to polynucleotides, while the claim of group III is drawn to an antibody. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention III would require searching in areas unrelated to polynucleotides, and as such, would require an undue burden on the examiner if not restricted.

Inventions I and (IV, V, and VIII-X) are not related. The claims of Group I are drawn to polynucleotides, while the claims of Groups (IV, V, and VIII-X) are drawn to a method of

making a polypeptide and to methods of using a polypeptide. While the polynucleotide of Group I may encode a polypeptide made by the method of Groups (IV-V), no such limitation is recited in the claims of either Group, therefore the Groups are separate and distinct.

Inventions I and (VI and VII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotides of Group I can be used in a materially different method, such as an amplification or sequencing reaction.

Inventions II and III are separate and distinct as the polypeptides of Invention II are structurally and biochemically different than the antibodies of Invention III. While the antibodies may bind to the polypeptides of Invention II, the biochemical activities of each Invention are quite different, requiring differing methods and areas of search, which would impose an undue burden upon the examiner.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the recombinant cells of Group II may be used in a process to make another polypeptide, in methods to study various aspects of cellular biology, etc. Whiles the cells of Group IV may express the polypeptides of Group II, such a limitation is not recited in the claims. In addition, the polypeptide produced n Group IV is not limited to be the polypeptide

of Group II, and may therefore be a different product. For these reasons, Groups II and IV are distinct.

Inventions II and (V and VIII-X) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide of Group II can be used in various process, as recited in the claims of Groups V and VIII-X), or in a another materially different process, such as making antibodies or in a purification assay. Group II is therefore distinct from each of Groups V and VIII-X.

Inventions II and VI-VII are not related. The claims of Group II are drawn to a polypeptide, whereas the claims of Groups VI-VII are drawn to methods of use of a polynucleotide and do not recite any relationship to or use the polypeptide of Group II. Group II is therefore separate and distinct from each of Groups VI and IX.

Inventions III and IV are not related. The antibody of Group III has no relationship to the method of making a polypeptide of Group IV, and as set forth above, antibodies and polypeptides are considered separate in the art, therefore the Inventions are separate and distinct.

Invention III is not related to any of Inventions V, VI, VII, VIII, IX, or X. The methods of Groups V, VI, VII, VIII, IX, and X do not recite the antibody of Group III, and the antibody of Group III is separate and distinct from any of the polynucleotides or polypeptides recited in the method claims, therefore Group III is separate and distinct from Groups V, VI, VII, VIII, IX and X.

Groups IV, V, VI, VII, VIII, IX, and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to methods which have different methods, starting materials, and goals.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants are permitted to elect a single nucleic acid sequence (See MPEP 803.04).

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements, and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alexander H. Spiegler
December 10, 2001

KENNETH R. HORLICK, Ph.D.
PRIMARY EXAMINER
GROUP 1600
12/10/01